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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/695,427 | 10/28/2003 | Kurt-Reiner Geiss | 7390-X03-020 | 4477 |

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| EXAMINER | |
|---|---|
| SPIVACK, PHYLLIS G | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/695,427 | GEISS ET AL. | |
| | Examiner | Art Unit | |
| | Phyllis G. Spivack | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 3-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Request for Continued Examination (RCE) filed June 15, 2006 is acknowledged and accepted. Claims 1 and 3-18 remain under consideration.

Upon reconsideration the Restriction Requirement that was set forth in the last Office Action is withdrawn. All claims will be examined in their entirety.

A complete list of all co-pending and related applications is requested when Applicants respond to this Office Action.

Claims 1 and 3-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, Applicant must convey with reasonable clarity, as of the filing date, that Applicant was in possession of the claimed invention. The issue of a lack of adequate written description also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996), (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Possession may be shown in many ways. For example, possession may be

shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that Applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. For example, a specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claims and determined that the invention would work for its intended purpose. An Applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Applicant was in possession of the claimed invention as a whole.

An Applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics that provide evidence that Applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to

practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicants have not conveyed possession of the invention with reasonable clarity to one skilled in the art. Claim 1 is drawn to a method for acceleration of a physiological recovery process of a body of a user after a physical exertion comprising administering an ingestible product including L-theanine. Broadly interpreted, the subject matter of the claim encompasses regaining any function of any part of the body of any living organism, including man, after any type of physical activity. Further, claims 10 and 17 are drawn to the physiological recovery of any central nervous system activity, any stress hormone, any circulatory behavior, heart rate, blood pressure, any brain wave activity or any electrodermal stress reaction. Claims 8, 9 and 11-18 are drawn to arbitrary designations, i.e., M1, M2, M3, M4 and M5, of intervals showing a human brain

at different times after physical or mental stressing. There is no reference provided as to a source of these arbitrary designations other than Applicants' own. There are no working examples directed to administration of L-theanine after physical and/or mental stressing wherein results in any of the parameters recited in claims 10 and 17 are disclosed. Applicants rely on Figure 1 in the specification to provide support for acceleration of a physiological recovery process of a body of a user after any physical exertion comprising administering an ingestible product including L-theanine, regaining any function of any part of the body of any living organism, including man, after any type of physical activity and to the physiological recovery of any central nervous system activity, any stress hormone, any circulatory behavior, heart rate, blood pressure, any brain wave activity or any electrodermal stress reaction. A review of the specification shows little more than conjecture. No working examples are provided that would describe to one of ordinary skill in the art an embodiment that meets all the limitations of the claims. Sufficient guidance to support predictable operability of the invention to one of ordinary skill in the art is absent. The art does not recognize efficacy in acceleration of a physiological recovery process after any mental and/or physical stress in diverse organ systems.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juneja et al., Trends of Food Science & Technology.

Juneja teaches the oral administration of L-theanine to promote relaxation, to promote the generation of α-brain waves, which are known to be generated during the relaxed state, and to lower blood pressure without inducing drowsiness. The dosage range is 50-200 mg. As disclosed on page 200 under Lowering blood pressure, L-theanine was administered to spontaneously hypertensive rats (SHR). In the SHR, blood pressure was already elevated prior to the administration of L-theanine. Blood pressure was measured before and after administration. See Figure 4 on page 202. Alpha waves are known to indicate an awake, alert and relaxed physical and mental condition. Juneja further discloses an enzymatic method to manufacture theanine on an industrial scale. The reference teaches L-theanine as an additive in candies, herb tea, cocoa drinks, beverages, chocolates, puddings, jellies, chewing gums and other confectionaries for its relaxation effect. Reference is made, in particular, to Figure 3 on page 201, where a showing of topographies converted from data of brain waves on brain surface is disclosed in ten-minute increments over 60 minutes after the intake of L-theanine in human volunteers. Figure (b) appears similar to instant Figure 1 with respect to $\alpha_2$ waves.

In view of Juneja's teaching, it would have been reasonable to expect the administration of L-theanine after stressing would result in the same relaxation effect. Such would have been obvious in the absence of evidence to the contrary because L-

theanine was administered to spontaneously hypertensive rats (SHR) wherein blood pressure was already elevated prior to the administration of L-theanine.

In the last Office Action, Claims 1-7 remained rejected under 35 U.S.C. 102(a) as being anticipated by Fischer et al., EP 1 275 309. It was asserted Fischer teaches the oral administration of L-theanine in the form of a food, such as a drink, for stress relaxation. Claims 1 and 3-7 were rejected under 35 U.S.C. 102(b) as being anticipated by Kanamichi et al., JP 09-012454 (abstract). It was asserted Kanamichi teaches the administration of theanine in a food product, obtained by allowing glutaminase to act on a mixture of glutamine with ethylamine, in dosages of 0.3-300 mg/kg body weight, to provide mental relaxation. Further, claims 1, 4 and 7 were rejected under 35 U.S.C. 102(b) as being anticipated by Wataru et al., JP6100442. It was asserted Wataru teaches the administration of theanine in a food product, such as a soft drink, obtained as a glutamic acid derivative to mitigate stress from mental or physical diseases.

In response to the three rejections of record under 35 U.S.C. 102, Applicants argue the administration of L-theanine took place after stressing.

Applicants' argument is not found persuasive because the prior art recognizes efficacy in the promotion of a relaxing effect in the parameter of lowering blood pressure in an animal model wherein hypertension is in place prior to the administration of L-theanine. Accordingly, the rejections of record under 35 U.S.C. 102 are maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

November 12, 2006